IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

JAZZ PHARMACEUTICALS, INC., Plaintiff, v. AVADEL CNS PHARMACEUTICALS LLC, Defendant.	C.A. No. 21-691 (GBW) [redacted] REDACTED - PUBLIC VERSION
JAZZ PHARMACEUTICALS, INC. and JAZZ PHARMACEUTICALS IRELAND LIMITED, Plaintiffs, v. AVADEL CNS PHARMACEUTICALS LLC, Defendant.	C.A. No. 21-1138 (GBW) [redacted] REDACTED - PUBLIC VERSION
JAZZ PHARMACEUTICALS, INC. and JAZZ PHARMACEUTICALS IRELAND LIMITED, Plaintiffs, v. AVADEL CNS PHARMACEUTICALS LLC, Defendant.	C.A. No. 21-1594 (GBW) [redacted] REDACTED - PUBLIC VERSION

PLAINTIFFS' REPLY IN SUPPORT OF
RENEWED MOTION FOR A PERMANENT INJUNCTION

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I. INTRODUCTION

It is undisputed that Avadel is enjoined from marketing, making, using, or selling Lumryz for IH until the '782 patent expires. Jazz's opening brief (D.I. 747) presented a step-by-step analysis of why it is necessary to enjoin Avadel from seeking IH approval to stop Avadel from further infringing Jazz's '782 patent dosage form claim 24 and violating the injunction. Jazz also demonstrated the *eBay* factors support the renewed injunction. Avadel fails to show otherwise.

First, despite Avadel's claims (D.I. 757, "Opp."), it is far from speculative that Avadel seeking FDA approval would result in Avadel violating the current injunction. Avadel is ***already*** selling Lumryz off-label for IH in violation of the injunction. Those sales would only increase. Avadel failed to present any evidence that casts doubt on whether its trial will be successful or whether the FDA will approve its application. Nor does Avadel's alleged promise to try its best not to infringe, as this Court has found, justify denial of an injunction. Avadel also mischaracterizes Federal Circuit law and fails to rebut expert testimony that an IH indication (and safety and efficacy results) would be added to Lumryz's label and doctors would follow those instructions, resulting in infringing sales and marketing in violation of the injunction.

Second, the *eBay* analysis favors Jazz. Avadel improperly focuses on a nonexistent constitutional right to seek FDA approval given that it is an adjudicated infringer. Avadel also relies on a flawed characterization of this Court's prior finding regarding the public interest.

II. ARGUMENT

A. Avadel Will Violate The Current Injunction Absent The Renewed Injunction

Avadel wrongly contends Jazz "implicitly admits" that any FDA submission by Avadel seeking an IH indication for Lumryz would not constitute infringement under 35 U.S.C. § 271(e)(2). Opp. at 3. But the infringement judgment in this case, and the injunction, is under § 271(a), not § 271(e)(2). D.I. 550, 598 (Trial Tr. at 890:16-21). And the question for the Court

is whether the renewed injunction is necessary to prevent Avadel's § 271(a) infringement in IH. *See* D.I. 747 at § III(A).

Avadel argues the renewed injunction is unnecessary because it "is contingent on future events." Opp. at 4. That argument finds no basis in law or the Federal Circuit's opinion. The Federal Circuit did not vacate the injunction because it was based on future events. Instead, it determined that this Court's previous analysis was "too speculative and tenuous to reasonably conclude from its findings that enjoining Avadel from applying for FDA approval is necessary to prevent future infringement." *Jazz Pharms., Inc. v. Avadel CNS Pharms., LLC*, 136 F.4th 1075, 1089 (Fed. Cir. 2025). That is because the factual record had not been developed, since Avadel never raised these issues with this Court until its emergency motion to stay. *Id.* at 1085. Jazz's opening brief addresses the Federal Circuit's concern. Avadel fails to show otherwise.

1. Avadel cannot credibly dispute that it intends to request FDA approval for IH and expects its request to be approved

Without any support, Avadel attempts to cast doubt on FDA approval for IH. Opp. at 5-6. But the FDA already determined oxybate—the active in both Xywav and Lumryz—is safe and effective for IH. D.I. 747 at 8-9; D.I. 748, Ex. C at 22-23 ("Considering [both drugs] have the same active moiety, . . . FT218 is expected to effectively treat IH."). Avadel argues its trial's outcome is not "guarantee[d]" (Opp. at 6), but a "guarantee" of continued infringement is not required. *Smith & Nephew, Inc. v. Synthes (U.S.A.)*, 466 F. Supp. 2d 978, 989 (W.D. Tenn. 2006) ("Although the record shows that [the infringing step] is not always essential," the court nonetheless enjoined all use of products capable of infringing). "[I]njunctions are tools for prospective relief designed to alleviate future harm" that issue based on both past and prospective acts of the infringer. *i4i Ltd. P'ship v. Microsoft Corp.*, 598 F.3d 831, 862 (Fed. Cir. 2010). Avadel is already selling Lumryz for IH; the evidence shows it will continue to do so.

In fact, since June 2023, Avadel has consistently stated it will complete its clinical trial; it expects the trial will succeed; and it expects FDA approval as soon as late 2026. D.I. 747 at 6-9. Avadel asks the Court to ignore its consistent public messaging based on boilerplate securities risk factor disclosures regarding purported "uncertainties." *See* Opp. at 5; *see also Southland Sec. Corp. v. INSpire Ins. Sols., Inc.*, 365 F.3d 353, 372 (5th Cir. 2004) (securities disclosures are "boilerplate" where they set forth a "litany of generally applicable risk factors" as opposed to "'substantive' company-specific warnings"). Avadel identifies no specific risk to its IH program (such as an adverse safety signal or threatened loss of funding), and instead invested an estimated $35-40 million in its IH indication. Ex. 7 at 64:16-17, 70:23-25. It is inconceivable to think Avadel will not seek an IH indication after making that level of investment. And Avadel's attempt to cast doubt on whether it will seek approval for IH is belied by the fact that Avadel continues to oppose the injunction and argue it should be allowed to seek approval.

Avadel's newfound uncertainties echo statements made at the injunction hearing that it would not run its trial if enjoined. Ex. 7 at 64:15-21; 85:25-86:8. But ***the next day*** Avadel said on "X" it would soon start the trial. Ex. 20. "In view of [Avadel's] . . . less-than-forthright behavior, . . . an injunction is highly necessary to protect [Jazz's] patent rights." *Global Traffic Techs. LLC v. Tomar Elecs., Inc.*, No. 05-756, 2009 WL 10678424, at *11 (D. Minn. Jan. 22, 2009); *see also Commodity Futures Trading Comm'n v. Wilshire Inv. Mgmt. Corp.*, 531 F.3d 1339, 1346-47 (11th Cir. 2008) (affirming injunction where infringer's "lack of candor . . . belies any intent of making good faith efforts to comply with restrictions in the future").

Contrary to what Avadel argues, it need not overcome Xywav's IH ODE to seek and receive IH approval before the '782 patent expires. Opp. at 6-7. Instead, as Avadel recognizes, if the renewed injunction were denied, Lumryz would either (1) be approved for IH with its own

ODE, or (2) not be approved for IH until Xywav's ODE expires in August 2028. But Avadel is wrong about the implications. For (1), Avadel wrongly assumes its continued infringement will have been justified and that the current injunction should be lifted. This Court already admonished Avadel's attempt to "just open[] the door for infringement" based on a potential ODE. Ex. 7 at 78:24-25. Also, the Court's decision not to enjoin for narcolepsy was not based solely on ODE; rather, it was based on Lumryz's use once-nightly (versus twice-nightly) ***and*** Lumryz already being on the market for narcolepsy. D.I. 665 at 21. For IH, Xywav may be dosed once nightly and Lumryz is not already on the market with an approved IH indication. *Id.* at 27-28. Avadel has not presented evidence to the contrary. *Id.* For (2), Avadel wrongly argues Jazz would suffer no harm. But Lumryz would still be approved for IH before the '782 patent expires (August 2028 versus February 2036), and Avadel would expand its infringement. If Jazz's request is denied, no matter which outcome occurs, this much is certain: IH will be added to the Lumryz label years before patent expiry, and Avadel will violate the current injunction.

2. Avadel's purported promise not to infringe lacks merit

Avadel admits that, once approved, Lumryz for "IH would no longer be 'off-label.'" Opp. at 9 n.1. And Avadel does not dispute that the IH indication and study results must be added to the label, and PBMs would cover IH. Avadel, instead, argues these facts are irrelevant because it "has proactively implemented various measures to stop sales for IH." *Id.* at 8. Not so.

First, as this Court has recognized, a "promise by a party in the course of litigation to discontinue past or ongoing misconduct does not justify denial of injunctive relief." *Natera Inc. v. ArcherDx, Inc.*, No. 20-125, 2023 WL 9103876, at *3 (D. Del. Dec. 1, 2023) (citation omitted). "[I]f the defendant sincerely intends not to infringe, the injunction harms it little; if it does, it gives plaintiff substantial protection." *Cartier, Inc. v. Four Star Jewelry Creations, Inc.*, No. 01-11295, 2003 WL 21056809, at *6 (S.D.N.Y. May 8, 2003) (cleaned up).

Second, Avadel presents no evidence that its so-called "measures" work to prevent sales of Lumryz for IH. Avadel argues it has (1) sent letters to pharmacies and insurance providers about the injunction; (2) checked that patients in its patient services program have narcolepsy; and (3) included in a call script that Avadel does not market or sell Lumryz for IH. Opp. at 8; D.I. 759 at ¶ 3. Measure (1) does not prevent pharmacies from providing Lumryz for IH and Avadel does not dispute that insurance providers will cover IH once approved. Measures (2) and (3) are also toothless as patients do not need to be in the patient services program to receive Lumryz, and the call script does not prevent patients from receiving Lumryz to treat IH. Further, Jazz requested Avadel remove "other" (as opposed to narcolepsy) as an indication from the Lumryz prescription form to ensure Lumryz is prescribed ***only*** for narcolepsy but Avadel did not do so. *See* Exs. 21-22. Avadel's attorney declaration (D.I. 761) conspicuously omits this fact.

Avadel also fails to address the elephant in the room: Avadel has already been selling Lumryz for non-narcolepsy uses post injunction. *See* D.I. 747 at 13; Opp. at 8 (admitting such sales are not limited "to patients prescribed LUMRYZ off-label before the injunction"). Further, Avadel works with dozens of sleep doctors in its trials and has retained at least five sleep doctors as experts in this case. Despite Jazz pointing out that Avadel's own declarant stated she will offer Lumryz to her IH patients as soon as it is approved (D.I. 747 at 13), Avadel did not provide a single declaration from an oxybate prescriber stating they would not prescribe Lumryz for IH once FDA approved. Thus, despite its ability to provide such evidence (if it existed), Avadel's opposition is bereft of any, let alone "very persuasive," evidence that would allow it to even present a no-risk-of-future-infringement argument, which further supports Jazz's renewed injunction. *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 842 F.2d 1275, 1281-82 (Fed. Cir. 1988).

Avadel's reliance on *Brooktrout* and *C.R. Bard* is misplaced. In *Brooktrout*, the court

"enjoin[ed] Eicon from publishing any document to be distributed in the United States which contains any [infringing] instructions to users." No. 03-59, 2005 WL 8160605, at *6 (E.D. Tex. July 25, 2005). This is what Jazz's requested injunction will do—Avadel does not dispute that Lumryz's label will include an IH indication once approved, and as explained, these are infringing instructions. *See infra* at § II.A.3. Avadel also misquotes *C.R. Bard*. There, the court ordered "U.S. Surgical to provide sufficient instruction to its customers to prevent future infringement." 258 F. Supp. 2d 355, 364 (D. Del. 2003). It did not, as Avadel misquotes, "reason[] that providing 'instruction to its customers' to not use the device in an infringing manner was less intrusive and 'sufficient to prevent future infringement.'" Opp. at 8. If the label includes an IH indication, Avadel cannot "provide sufficient instruction to its customers to prevent future infringement" and thus *C.R. Bard* supports Jazz. *See infra* at § II.A.3.

3. FDA approval would necessarily lead to marketing and sales for IH

Avadel admits, once Lumryz is approved for IH, IH must be in its label. It also has no response to Jazz's experts (Mr. Cortez and Dr. Bogan) that Avadel would be required to disseminate marketing materials consistent with its labeling and doctors would prescribe in accordance with those materials. *See* D.I. 749 at ¶¶ 20, 37; D.I. 748 at ¶¶ 13-42; *see also Frei v. Taro Pharms. U.S.A., Inc.*, 443 F. Supp. 3d 456, 467 (S.D.N.Y. 2020) (Drug company "could not have disseminated post-marketing warnings inconsistent with [the] warnings and labeling—approved by the FDA—without violating federal law."). Avadel argues this will not negate the current injunction because "Jazz has not provided any basis to infer an intent to infringe by Avadel" because of alleged "preventative measures which negate any alleged specific intent." Opp. at 12. Jazz already addressed this argument above. Moreover, Avadel has since told the investment community the opposite—that for "the IH patient population [it] will customize [its] marketing and promotional approach to really drive expansion of that market." Ex. 23 at 13.

Avadel also fails to address *Braintree Labs. v. Breckenridge Pharm.* (cited in Jazz's opening brief), which holds that where the indication in the label "instructs how to engage in an infringing use, it shows an affirmative intent that the product be used to infringe." 688 F. App'x 905, 910 (Fed. Cir. 2017) (cleaned up). Instead, Avadel wrongly argues an infringing label is only "infringing marketing," and "'[m]arketing' is not itself infringement." Opp. at 14. *First*, Avadel ignores that including IH in the label will result "in Avadel marketing ***and selling*** Lumryz for IH." *See* D.I. 747 at § III(A)(3) (emphasis added). Selling is infringement. *Second*, Jazz need not show intent. Claim 24 is a dosage form, not a method, and Avadel already admitted Lumryz infringes that claim. *Third*, Avadel overlooks that it is already enjoined from "marketing" Lumryz for IH; it is undisputed that portion of the injunction remains post-appeal.

As such, Avadel argues it "does not market LUMRYZ for any non-narcolepsy indication and will continue to refrain from doing so as long as the Court's injunction remains in effect." Opp. at 14. But Avadel badly misreads the case-law on which it relies for this argument.

Relying on *Genentech, Inc. v. Sandoz Inc.*, 55 F.4th 1368 (Fed. Cir. 2022), Avadel contends that "[e]ven if LUMRYZ is approved for IH, LUMRYZ marketing materials will make clear that LUMRYZ is enjoined from being sold for any non-narcolepsy indications, including IH. In such circumstances, the existence of the label alone cannot constitute marketing." Opp. at 15. Setting aside that Avadel fails to contest it would not receive FDA approval for marketing material that contradicts its FDA-approved labeling (*see supra* at 6), *Genentech* involved a very different label than the one Avadel would have. In *Genentech*, the patented methods related to the co-administration of the drugs pirfenidone and fluvoxamine. *See* 55 F.4th at 1374. The accused label did not recommend co-administration of those drugs. To the contrary, the label stated that "concomitant administration" is "***not recommended***" and the "[u]se of fluvoxamine

. . . should be ***discontinued*** prior to administration of pirfenidone and ***avoided*** during pirfenidone treatment." *Id.* at 1375 (emphasis added). In fact, the Federal Circuit recently confirmed that "Genentech's label actually instructed you not to do [the patented method]." Ex. 24, *Corcept Therapeutics, Inc. v. Teva Pharms. USA, Inc.*, No. 24-1346, Oral Arg. Tr. (Fed. Cir. July 7, 2025), at 26:4-9; *see also id.* at 25:23-24. Here, Avadel's label would do the opposite—it would expressly tell doctors to prescribe the infringing Lumryz dosage form for IH.

Avadel further argues that "the Federal Circuit recently explained that in evaluating a non-Hatch-Waxman case, the question of whether a party is encouraging infringement is not determined solely by examining the label language." Opp. at 15-16 (citing *Amarin Pharma, Inc. v. Hikma Pharms. USA Inc.*, 104 F.4th 1370, 1379 (Fed. Cir. 2024) and *Metacel Pharms. LLC v. Rubicon Rsch. Priv. Ltd.*, No. 21-19463, 2023 WL 5939903, at *3 (D.N.J. Sept. 12, 2023)). Neither case supports Avadel. In *Amarin*, the accused infringer had "carve[d]-out" or removed the infringing indication from its label. *See* 104 F.4th at 1373. Still, the Federal Circuit held that the patentee could rely on other evidence (e.g., marketing materials) at the pleadings stage to show the defendant nonetheless intended physicians practice the carved-out method. *Id.* at 79. It strains credulity to suggest that holding extends to the inverse situation here (where Avadel's label would expressly include the forbidden indication). In fact, as the *Metacel* case on which Avadel further relies makes clear, "the label is what matters, because that is what the downstream users—healthcare practitioners, pharmacists, or patients—will rely upon." 2023 WL 5939903, at *4. Simply put, this is not a case where the label would "merely describe the infringing use" as Avadel contends—the infringing use would be the indication itself.

There is not a single case where non-infringement exists based on statements encouraging action ***not in accordance*** with the label. Avadel cannot "separat[e] out the infringing uses" for

IH from its labeling upon FDA approval, which provides sufficient justification for the renewed injunction. *Nat'l Instruments Corp. v. MathWorks, Inc.*, 113 F. App'x 895, 899 (Fed. Cir. 2004).

B. The *eBay* Factors Support Jazz's Renewed Injunction

The Federal Circuit rejected Avadel's *eBay* arguments, including regarding ODE, for the injunction preventing marketing, making, using, or selling Lumryz for IH through the expiration of the '782 patent. *Jazz*, 136 F.4th at 1089. The Federal Circuit only questioned the connection between the Court's finding of irreparable harm and enjoining Avadel seeking IH approval and thus ordered the Court to "address the *eBay* factors anew in accordance with this opinion before again enjoining ***that*** activity." *Id.* (emphasis added). Jazz demonstrated in its opening brief why the *eBay* factors support the renewed injunction. Avadel fails to rebut Jazz's showing.

1. Irreparable Harm/Inadequacy of Monetary Remedies

As explained in Jazz's opening brief and above, Avadel seeking IH approval will inevitably result in Avadel selling more Lumryz for IH, irreparably harming Jazz. D.I. 747 at 3-19; *see also supra* at § II.A. Thus, Avadel is incorrect that Jazz "has not attempted to show any causal nexus between approval and any alleged harm." Opp. at 9.

Avadel also argues, contrary to case law and this Court's prior holding, that "lost sales, lost market share, and price erosion are all redressable with money damages" and faults Jazz for not "calculat[ing] such damages" or detailing "the amount of market share it stands to lose." Opp. at 9-11. Avadel cites no authority, and this Court and the Federal Circuit have held the opposite. *See* D.I. 665 at 4-5, 10-12, 22-24; *Jazz*, 136 F.4th at 1088-89. Avadel's complaint that Jazz has not calculated losses that this Court has already held cannot be calculated is nonsensical.

2. Balance of Equities

Avadel's arguments (Opp. at 19-20) lack merit. *First*, as explained above, Avadel's alleged preventative measures fail. *See supra* at § II.A.2. *Second*, Avadel has no right to

"demonstrate LUMRYZ's clinical superiority to XYWAV for IH," nor does Avadel need to for approval. Opp. at 16-18. Avadel is an adjudicated infringer, and the Federal Circuit confirmed seeking FDA approval is not safe harbor activity. *Jazz*, 136 F.4th at 1085-86. Enjoining seeking FDA approval is necessary to stop expanded infringement and violation of the current injunction. D.I. 747 at 4-15; *supra* at § II.A. Such conduct can and should be enjoined. *Jazz*, 136 F.4th at 1088. *Third*, the Federal Circuit already "considered" and found "unpersuasive" Avadel's First Amendment argument.[1] *Jazz*, 136 F.4th at 1089. "Reasonable restraints may be placed on an infringer to both eliminate the consequences of past bad acts and to prevent further encroachment on the patent." *Eli Lilly & Co. v. Medtronic, Inc.*, 735 F. Supp. 652, 662 (E.D. Pa. 1990) (rejecting First Amendment argument), *vacated on other grounds,* 915 F.2d 670 (Fed. Cir. 1990).

3. Public Interest

Avadel's argument relies solely on a hypothetical ODE that this Court already said should not "just open[] the door for infringement," Ex. 7 at 78:24-25, and that the Federal Circuit already rejected. *Jazz*, 136 F.4th at 1089. ODD (which requires only a plausible hypothesis of alleged superiority rather than actual evidence) does not "fundamentally change[] the landscape." Opp. at 20. Indeed, "[a]ccording to OOPD data, 7 percent of 2,615 orphan designations granted from 2008 to 2017 resulted in [ODE, which requires clinical evidence]." Ex. 25 at 23 n.34. And as explained, Xywav is already approved for once-nightly treatment of IH, so the injunction would not deprive patients who desire a once-nightly oxybate of that option regardless of ODE.

III. CONCLUSION

The Court should grant the renewed limited permanent injunction requested in D.I. 746.

[1] Avadel's waiver argument is misplaced. Jazz may respond in its reply to Avadel's arguments made for the first time in Avadel's answering brief. *Cephea Valve Techs., Inc. v. Abbott Labs.*, No. 23-691, 2024 WL 3291632, at *3 (D. Del. Apr. 19, 2024) (Williams, J.).

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CERTIFICATE OF SERVICE

I hereby certify that on August 19, 2025, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

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